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10/036,072	10/19/2001	Lars Hoff	43707.12.1	3928

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,072

Applicant(s)

HOFF ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 32-48 and 62-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18-28, 31 and 49-61 is/are rejected.
- 7) ☒ Claim(s) 16, 17, 29 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-31, 49-61, drawn to Method and Apparatus for Non-linear Bone Measurements, classified in class 600, subclass 449.
- II. Claims 32-41, 44-48 drawn to Methods for Shear Wave Lamé Coefficient or Shear Wave Velocity Determination, classified in class 73, subclass 597.
- III. Claims 42-43, drawn to Method for Combined Pressure and Shear Wave Bone Measurements, classified in class 600, subclass 438.
- IV. Claim 62, drawn to Angulated Arrival Time Speed of Sound Measurement, classified in class 73, subclass 597.
- V. Claims 63-65, drawn to Acoustic Surface Wave Velocity Measurement, classified in class 600, subclass 449. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions II – V have separate utilities such as in association with specific bone or materials measurement methods and systems not requiring harmonic or beat frequency processing of acoustic characterizing information.

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Because these inventions are distinct for the reasons given above and the search required for Group s II - V is not required for Group I, restriction for examination purposes as indicated is proper.

During a telephone conversation with John Dolan, Reg. No. 45,382 on 2-11-04 a provisional election was made with~~out~~ traverse to prosecute the invention of Group I, claims 1 – 31 and 49 - 61. Affirmation of this election must be made by applicant in replying to this Office action. Remaining claims stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

Claim 61 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 60. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In this instance the slight difference in wording 'device' versus 'system' results in substantial duplication of the claim content since both terms simply pertain to 'apparatus'. A nut and bolt for example is a fastening system; a vast plurality of parts may constitute into a device for recording music and so forth.

Applicant is advised that should claim 61 be found allowable, claim 62 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

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claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

[Parenthesized claim numbers pertain to the specific application claim(s) against which the particular rejection comment is directed..]

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 3, 18-20, 49-50 52-53, 55, 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaufman et al (US5259384). Kaufman et al teaches arranging transmit/receive transducers 12, 13 so as to determine non-linearity within the bone, attenuation measurement and also group velocity functions and phase derivative as a function of frequency being non-linear processes, see col. 2 lines 46-64 and col. 6. for purposes of determining diminished bone density and strength (Claims 1-2, 55). The degree of variance of measured regional data for group velocity and specific attenuation is effectively an index of regional heterogeneity of bone, see col. 10 lines 47-54. (Claims 3, 50). Since Kaufman et al uses plural non-linear techniques as noted, any of these constitute “other measurement techniques” with respect to the former. (Claims 18, 52).

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For example frequency-specific attenuation alongside the group velocity/phase derivative, see col. 8 lines 8-11. (Claim 20). One embodiment uses reflected ultrasound to compute intervening soft tissue thickness, see col. 7 lines 21-42. (claims 19, 53). Phase velocity is discussed as a function of frequency and bone member length and as an intermediate to group velocity determination, see col. 8 line 51 – col. 9. (Claim 49).

Kaufman et al (US5259384) specifically teaches a device for measuring phase velocity as a function of frequency, see col. 3 lines 26-35..(Claims 60-61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as argued against claim 1 above, and further in view of Passi et al (US6322507) or Winder (US6213958). Since Passi et al note in col. 8 that nonlinearities due to higher order harmonics limit the frequency at which meaningful analysis may occur for their technique, it would have been obvious in view of the latter to track the second harmonic or plural higher harmonics in order to ensure measurement integrity where bone analysis such as Kaufman et al is practiced in

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wideband fashion. In the alternative, Winder, directed to ultrasound but termed 'acoustic' (col. 5 line 43 – col. 6 line 6) teaches that non-linear coherence functions between frequencies may serve to characterize bone as pertains to frequency dependent phenomena as in Kaufman et al in the fashion of component wear characterization ion machinery, col. 9 lines 32-38, and this is understood to embrace harmonic component(s) studies since harmonic distortion of the measurement system components themselves is pre-compensated, see col. 7 lines 26 – 46.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as applied to claim 1 above, and further in view of Winder '958, further in view of Greenleaf et al (US5903516). Winder et al teaches as aforementioned the production of non-linearity information as cross-correlation between differing frequencies in order to characterize bone. It would have been obvious in view of Greenleaf et al to use beat frequencies to analyze such properties since intermodulation would be readily detected by Winder's intermodulation scheme. (Claims 8, 10). Since Winder expands upon Kaufman et al' two – transducer through transmission in the sense of providing an array 16 for transmission and reception, the transmission and reception may additionally occur onto the same or other than the transmitting transducer(s). (Claims 9, 11-14).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as applied to claim 1 above, and further in view of Winder '958 and Greenleaf et al as combined above, further in view of Passi et al. As noted above, the latter identifies frequency harmonics harmonics in order to eliminate distortion in bone

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measurements, hence this would be advantageous to incorporate in a system measuring bone material properties by sum and differencing, albeit the harmonic does not produce a bone quality measurement..

Claims 21, 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as applied to claim 1 or 52 above, and further in view of Passi et al. It would have been obvious in view of the latter to provide a speed of sound measurement to characterize bone since Passi et al notes col. 1 line 24 – col. 2 line 65 that SOS measurements are a well-known category of bone quality measurement technique.

Claims 22, 25-27, 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as applied to claim 1 or 49 above, and further in view of Pratt Jr et al (4913157). It would have been obvious in view of the latter, Col. 2 lines 23-24, col. 14 lines 20-25 to use elasticity measurements as an adjunct technique or as an output format for the ultrasound measured intermediates since this allows longevity tracking as well as a relatable parameterization of bone pathology. (Claims 22, 57). Pratt, Jr et al note col. 1 top that osteoporosis is by definition low bone density in its clinical context hence one may argue that while Kaufman et al does not explicitly so state, onset diagnosis of osteoporosis would be a major application of the Kaufman et al teaching. (Claim 25). Bone strength per se is one index produced by Kaufman et al, see abstract (claim 26). Pratt Jr et al advocates using a database on the same patient to track progress/deterioration. (Claim 27).

Claims 23 – 24, 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as applied to claim 1 or 49 above, and further in view

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of Greenleaf et al, alone or further in view of Winder (US6585647). Greenleaf et al teaches imaging of the determined mechanical properties such as identified in Kaufman et al, an image being a conventional qualitative measure of anatomic shape and dimensions. In the alternative, Winder Fig. 3 step 66 and col. 7 lines 45-51 teaches tissue shape and dimensional measurement for bone characterizations such as in Kaufman et al.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al in view of Pratt Jr et al as applied to claim 25 above, and further in view of Greenleaf et al, as the latter was applied regarding beat frequency use for material hardness parameterization above..

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al in view of Pratt, Jr et al as applied to claim 25 above, and further in view of Passi et al or Winder '958, as the latter were discussed regarding harmonic production supra.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as applied to bone analogous to compression parameters, see col. 9 lines 27-35, and for which shear modulus

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al as applied to claim 52 above, and further in view of Buhler et al (US5592943), since the latter advocates collection of scattered information as an adjunct to specular reflection for characterizing bone, see col. 9 lines 20-34.

Allowable Subject Matter

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Claims 16 – 17, 29 - 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Kantorovich et al (US5426979), Kwon et al (US5143069) are cited as of interest as directed to transverse bone propagation measurements.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

2-15-04



Francis J. Jaworski
Primary Examiner